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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-----------------------|
| 10/696,536 | 10/29/2003 | Leonard M. Patt | 480048.458 | 7818 |
| 500 | 7590 | 12/01/2004 | EXAMINER | |
| SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 6300 SEATTLE, WA 98104-7092 | | | | HEARD, THOMAS SWEENEY |
| | | ART UNIT | | PAPER NUMBER |
| | | 1654 | | |

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/696,536 | PATT, LEONARD M. | |
| | Examiner | Art Unit | |
| | Thomas S Heard | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-52 is/are pending in the application.
 - 4a) Of the above claim(s) 3-19 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-2 and 20-52 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: a composition comprising at least one peptide copper complex and a metalloproteinase inhibitor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of metalloproteinase inhibitor for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 9, 12-21, 23-52 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made on November 18, 2004 for an election of species and attorney Emily Wagner requested to contact her client for the election. Emily Wagner called November 22, 2004 and left a voice mail message stating that her applicant elected the species MDI in claims 20-22. Claims 3-19 are currently withdrawn

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-2, and 20-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallenberg et al (U.S. Patent 5,538,945), Pickart (U.S. Patent 4,760,051), Dupont et al (U.S. Patent Application 2003/0087830 A1), Kelly, G.S. Alternative Medicine Review (1998) and Atrium Biotechnologies product information brochure.

Pallenberg et al teaches copper complexed with peptides, both dipeptides and tripeptides, in addition to C-terminal aryl derivatives of those copper complexing compounds, column 10 and Table 3. Pallenberg et al teaches the GHK, AHK, VHK peptides in percent and total weight ranges of the claims in the instant application, column 9 and lines 10-14, in addition to the copper to peptide ratios of the instant

application, columns 7 and lines 34-50. Pallenberg et al further teaches compositions of the above copper complexing peptides formulated for intradermal injections and for lotions, gels, and creams for topical administration and formulations for iontophoresis and liposome delivery, column 8 and lines 53-67 and column 9 and lines 1-51.

Pallenberg et al teaches a method of use of the copper-peptide complexes in the treatment of hair loss. Pallenberg et al does not teach the composition of a copper-peptide complex in combination with a metalloproteinase inhibitor from cartilage or MDI complex.

Pickart (U.S. Patent 4,760,051) teaches the GHK peptide as a wound healing and anti-inflammatory agent and Pickart (U.S. Patent 5,118,665) further teaches the same copper-complexing peptides as anti-oxidative compounds formulated in pharmaceutical acceptable carriers, lotions, creams and gels of the instant application.

Dupont et al teaches peptide copper complexes such as the GHK of the instant application for the treatment of wounds, page 1, and section [0015] and also teaches peptide-copper complexes in the presence of cartilage extract from shark that has anti-collagenase properties, page 13 and section [0173].

Kelly, teaches that cartilage consists of fibrous collagen composed of glycosaminoglycans, page 28. The MDI (Marine Derivative Isolates) Complex disclosed by Atrium Biotechnologies consists of glycosaminoglycans (CAS 94945-04-7).

It would have been obvious to one of ordinary skill in the art to modify the composition of Pallenberg by the inclusion of glycosaminoglycans derived from fish, shark, or MDI Complex as taught by Dupont. One would have been motivated to do so

given the desired anti-collagenase activity of glycosaminoglycans that are a major component of cartilage as taught by Kelly and Atrium Biotechnologies. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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